IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Jon Carl Marlowe et al.	Confirmation No.:	9078
Serial No.:	10/734,063	Art Unit:	1631
Filed:	December 10, 2003	Examiner:	Jason M. Sims
For:	AUTOMATED SYSTEM AND METHOD FOR PREPARING AN ASSAY READY BIOLOGICAL SAMPLE	CAM No.:	301891-999224
		Attorney Docket No.:	9301-232-999
		Date: February 28, 2007	

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants hereby request review of the Final Rejection mailed November 30, 2006 ("Final Rejection") of the above-identified application prior to filing an appeal brief for the reasons set forth below. A Notice of Appeal is included with this submission.

Independent claim 14 is provided below:

14. (Original) A computer implemented method for preparing a binding-ready biological sample for a binding assay, comprising:

receiving a binding assay design for a binding assay;

preparing an experiment design for generating a binding-ready biological sample to be used in said binding assay;

choosing a robot method for generating said binding-ready biological sample;

generating work instructions for generating said binding-ready biological sample based on said experiment design and said robot method; and

executing said work instructions on robot stations to generate the binding-ready biological sample.

REMARKS

The Office Action rejected claims 14-22 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,780,423 (Bluestein et al.) in view of U.S. Patent No. 6,996,538 (Lucas).

Applicants submit that the cited references of Bluestein et al. and Lucas, when considered in combination or when considered separately, would not teach or suggest the features as recited above in claim 14.

Initially, Applicants note that Bluestein is directed to heterogenous fluorescence assays using controlled pore glass particles. More specifically, in the Bluestein patent, a binding-ready biological sample for a binding assay is ferritin. The binding assay is the immunoassay, and the anti-ferritin antibody is a reagent in the binding assay. Applicants submit that nothing has been found in the Bluestein reference that would teach or suggest to a person of ordinary skill in the art a computer implemented method for **preparing a binding-ready biological sample** (ferritin) for a binding assay (immunoassay). The Bluestein reference only describes an automated method for the immunoassay.

The Office Action at page 3, 2nd full paragraph, states that "Bluestein et al. teaches the second step of claim 14 at col. 8, lines 10-31." Applicants submit that nothing in this section would teach or suggest preparing an experiment design for generating a binding-ready biological sample to be used in said binding assay. Column 8, lines 10-31 of Bluestein describes changes made in the radioimmunoassay protocol, materials, and equipment. For example, in the statement at col. 8, lines 22-24, that "300 ul of solid phase (CPG) anti-ferritin antibody was employed to which was added 150 ul of sample" the sample is already prepared and binding-ready prior to adding the anti-ferritin antibody reagent. These changes pertain to the actual immunoassay, not the sample preparation as recited in claim 14. In addition, the Bluestein reference discloses at column 7, lines 20-25, incubating the solid phase antibody with 200 ul of sample standards. Applicants submit that this section teaches that the samples are binding-ready and already prepared, i.e., there is no description of preparing the sample as recited in claim 14.

The Office Action at page 3, 3rd full paragraph, states that "Bluestein et al. teaches the third step of claim 14 at col. 8, lines 61-69 and col. 9, lines 1-30. Applicants submit that nothing in this section would teach or suggest preparing an experiment design for generating a binding-ready biological sample. The Pandex Screen Machine described in these sections automatically perform the immunoassay, i.e., nothing in these sections would teach or suggest preparing a binding-ready biological sample for a binding assay. More specifically,

in Bluestein, column 9, lines 17-29, states that "30 ul of the CPG reagent were added to each well of the microtiter plate followed by 30 ul of the standard." The "standard" is the binding-ready biological sample. The standard is already prepared when it is added to the plate. In other words, nothing in Bluestein has been found in these sections or any other sections that would teach or suggest preparing the sample as recited in claim 14.

Applicants note further that the MacCrindle et al. (Clin. Chem. 31:1487) reference submitted in the Amendment dated August 29, 2006, describes the Pandex machine in greater detail. In particular, the MacCrindle reference at page 1488, 1st paragraph states: "The samples are diluted with the Digiflex Pipetting Station and pipetted into the Epicon assay plate. Once the reagents and Epicon plates are loaded and the basic instrument parameters are selected, all further operations are completed automatic...." The samples are clearly binding-ready and prepared prior to adding to the Epicon plates and loading into the Pandex machines.

Moreover, the MacCrindle reference at page 1488, 2nd paragraph states: "Using the Digiflex pipettor, we make two serial diultions of the sample...Fifty microliters of this dilution of sample is pipetted into a well of the Epicon assay plate. Then, to each well the Screen Machine adds 20 ul of the 2.5 mg/mL suspension of antibody-coated particles...." Again, this section clearly describes that the samples are prepared and binding ready prior to processing by the Screen Machine. The Screen Machine only performs the immunoassay – i.e. adding the reagents, incubations, washes (see 2nd paragraph p. 1488 of MacCrindle).

In addition to the points made above re claim 14, Applicants note that it does not agree with a number of the Examiner's characterizations of Bluestein et al. and Lucas in the Office Action in relation to dependent claims 15-22 and in the *Response to Arguments* section starting on page 5 of the Office Action. For example, in regard to claim 15, the Office Action at page 3, in the beginning of the last paragraph, states that Bluestein et al. teaches optimizing materials usage and plate layout for generating a biological sample at col. 8, lines 15-26 and lines 53-57. Applicants disagree with the Examiner's characterization of these sections. More specifically, Applicants submit that nothing in these sections of Bluestein would teach or suggest optimization for generating a biological sample, but rather optimization for an immunoassay. These sections describe addition of anti-ferritin antibody, incubation, washes, and addition of fluorescein labeled anti-ferritin antibody, which are all steps in an immunoassay protocol.

In addition, the Office Action at page 5, last paragraph, and page 6, first paragraph, states that "This argument is not persuasive because Bluestein, at col. 9, lines 1-12, does disclose the automation of performing the particle concentration fluorescence immunoassay

and specifically states at col. 9, lines 12-15, that this same automated Screen Machine was used to perform the 2 site immunometric assay for ferritin as described in Examples 1 and 2." Applicants submit that the particle concentration fluorescence immunoassay is a binding assay; it is not a method for generating a binding-ready biological sample. As stated above, the samples in Bluestein are already binding-ready when the automated immunoassays are performed. The 2 site immunometric assay for ferritin performed by the Screen Machine is the particle concentration fluorescence immunoassay.

Moreover, the Office Action at page 6, first paragraph states that "Examples 1, 2, and 3 all have automated preparations and these examples describe the automated assay experiments being performed and specifically disclose the preparation of adding the controlled pore glass (CPG) antibody and adding the fluorescein labeled anti-ferritin antibody to each tube, which represents 'a robot method for generating said binding-ready biological sample' because of the automated processes." Applicants submit that examples 1, 2, 3 do not have automated preparations. The examples are silent on how the samples are prepared prior to being added to the immunoassay as binding-ready samples. The adding of controlled pore glass (CPG) antibody and fluorescein labeled anti-ferritin antibody are steps in an immunoassay, i.e. adding the reagents to the binding-ready biological sample (ferritin), and does not represent "a robot method for generating said binding-ready biological sample."

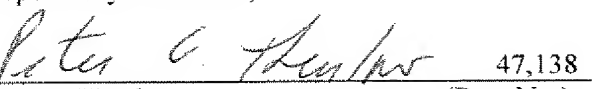
The Office Action at page 6, last paragraph also states that "The automated deposit of the CPG antibody to each tube followed by the deposit of the fluorescein labeled anti-ferritin antibody to each tube demonstrates the preparation of a binding-ready biological sample." Again, Applicants submit that the CPG antibody and fluorescein labeled anti-ferritin antibody additions are steps in a binding assay, i.e., they do not deal with preparing a binding-ready biological sample as required by claim 14. These antibodies are added to a binding-ready biological sample. Both the CPG anti-ferritin antibody and the fluorescein labeled anti-ferritin antibody bind to the binding-ready biological sample (ferritin). Addition of binding reagents to a binding-ready biological sample is not the preparation of a binding-ready biological sample.

At least for the reasons cited above, Applicants request that this application be allowed or be reopened for prosecution.

Applicants' undersigned attorney may be reached in our New York Office at the phone number below. All correspondence should continue to be directed to our address listed below.

Respectfully submitted,

Date: February 28, 2007



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PTO/SB/33 (07-05)
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Docket Number (Optional): 9301-232-999

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Application Number	Filed
10/734,063	December 10, 2003

First Named Inventor: Jon Carl Marlowe et al.

Art Unit	Examiner
1631	Jason M. Sims

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 47,138

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

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February 28, 2007
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.